

BETADINE® ANTISEPTIC LIQUID 10%w/v

Please read the insert before use. For further information, please contact your doctor or pharmacist.

Product Description

BETADINE® Antiseptic Liquid is formulated with 10%w/v povidone-iodine as a solution that kills 99.99% of germs* causing wound infection within 60 seconds.

* Kills gram-positive germs causing wound infection - *S. aureus*, *S. pyogenes*, *S. epidermidis*, *S. haemolyticus*, *C. albicans*, *P. acnes*.

Kills gram-negative germs causing wound infection - *E. coli*, *P. aeruginosa*, *B.fragilis*, *K.pneumonia*.

Active ingredient: Povidone-iodine 10%w/v

Composition: Glycerol, Laureth-9, Disodium Phosphate, Citric Acid Monohydrate, Sodium Hydroxide Potassium Iodate, Purified water.

BETADINE® Antiseptic Liquid 10% w/v is a brown-coloured povidone iodine solution, which is free from suspended material or sedimentation

Supplied in high-density polyethylene bottles containing 15ml, 30ml, 120ml, 125ml, 250ml, 500ml and 1000ml. Not all pack sizes may be marketed.

What is this medicine used for?

BETADINE® Antiseptic Liquid is indicated for

- Management of minor wounds, including prevention of infection in burns, cuts, and abrasions
- Disinfection for hand hygiene including during periods of infectious disease outbreaks
- Disinfection of the skin before an operation

How much and how often should you use this medicine?

For external use only.

Wounds, burns, cuts and abrasions:

Apply the solution, undiluted, onto areas to be treated and allow to dry. Air- permeable film is formed which can be easily washed off with water. The solution can be applied several times daily, for maximum of 14 days.

Disinfection of the hands:

Apply onto the palm and lather with hands and fingers for up to 1 minute. The natural golden brown colour of **BETADINE® Antiseptic Liquid** easily identifies the areas that has been washed. Areas that are not golden brown in colour indicates further handwashing is required. Rinse thoroughly with water. **BETADINE® Antiseptic Liquid** is not recommended for continuous daily use throughout the year.

Before surgery:

Apply to all areas of skin with special attention to skin folds such as the arm pit, groin and anal area. Avoid pooling both under the patient and in the skin folds. Skin burns due to 'pooling' may occur.

Remove any jewelry before use especially silver articles.

BETADINE® Antiseptic Liquid should not cover large areas of the skin (e.g. not to cover more than 10% of the total body surface) and for not longer than 14 days.

What should you do if you miss a dose?

If it is almost time for you to apply the next dose, skip the dose you missed, and apply your next dose when you are meant to.

What other products you should avoid whilst taking this medicine?

Other antiseptics or medications can affect how **BETADINE® Antiseptic Liquid** works. Avoid preparations containing hydrogen peroxide, silver, taurolidine or octenidine.

Tell your doctor if you are using BETADINE® before any diagnostic test.

Effects on Ability to Drive and Use Machinery

BETADINE® Antiseptic Liquid does not affect your ability to drive or use machinery.

When you should not use?

BETADINE® Antiseptic Liquid should not be used:

- If you are allergic to povidone iodine or any ingredients in the product
- If you have a thyroid problem
- If you are to receive or are currently receiving radioactive iodine treatments
- If you are using products containing mercury such as thiomersal
- In children under 1 year of age

Only use if agreed with a healthcare professional:

- If you are pregnant or breast feeding
- In children between 1 to 2 years of age

Consult a healthcare professional/ hospital immediately if:

- You have an allergy or skin irritation such as redness, small blisters, irritation, swelling, itching, or a rash which may occur immediately
- Symptoms do not improve or worsen
- Accidentally swallowed
- You have received radioactive iodine treatment within the last 4 weeks

Undesirable effects/side effects

- **BETADINE® Antiseptic Liquid** can cause side effects such as skin irritation, discolouration, redness, swelling, small blisters, itching, or dry skin, tiredness, weakness, confusion, rapid shallow breathing, passing little or no urine, fluid retention and swelling of legs, ankle and feet.
- Overactive thyroid symptoms may include feeling nervous, moody, difficulty in sleeping, trouble breathing, fast or irregular heartbeat, feeling hot and sweaty.
- Increased amounts of acid in the blood (symptoms include shortness of breath, confusion and lethargy),
- Kidney failure (symptoms include difficulty in urinating, thirst, dry mouth, and pain in one side of the back) have been reported with large amounts of **BETADINE® Antiseptic Liquid**.

Tell your doctor or pharmacist immediately if you have any of the following signs or symptoms:

- Allergic reactions that occur quickly and include an itchy raised skin rash (hives), a body rash, sudden breathing problems, feeling faint, swelling of the mouth, face, lips, tongue or throat – **seek medical help straight away**
- Symptoms of a thyroid problem may include feeling nervous, moody, difficulty sleeping, hand tremors, fast or irregular heartbeat, trouble breathing, feeling very hot or sweaty, weight loss, weight gain and tiredness.

If accidentally swallowed or comes in contact with the eyes, seek medical advice immediately.

How should you keep this medicine?

Store at or below 30°C. Do not store in your vehicle.

Keep out of reach of children.

Shelf-life:

3 years from the date of manufacturing. Do not exceed the expiry date stated on the label.

Manufactured by:

Mundipharma Pharmaceuticals Ltd., 13 Othellos Street, Dhali Industrial Zone, Nicosia, Cyprus

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